



MONTANA WHOLESALE FOOD LICENSING GUIDE

Department of Public Health and Human Services
Food and Consumer Safety Section
1400 Broadway Street – Room C214
Helena, MT 59620-2951
Telephone: 406-444-2837
Web: <http://www.dphhs.mt.gov/publichealth/fcs/index.shtml>

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The purpose of this document is to help prospective applicants comply with local, state and federal requirements for a wholesale food business. This document provides basic information on how to obtain a license to sell or serve foods at the wholesale level.

There are five steps that should be followed to obtain a license as a wholesale food establishment:

1. DETERMINE WHETHER A LICENSE IS REQUIRED
2. SUBMIT FOOD FACILITY PLAN
3. SUBMIT FOOD PROCESSING PLAN AND LABELING EXAMPLES
4. LICENSING PROCEDURE
5. FDA REGISTRATION

1. DETERMINE WHETHER A LICENSE IS REQUIRED

Wholesaling is providing food for human consumption that is not directly sold or distributed to the consumer. In other words, food that is sold or distributed to retailers.

The term “wholesale” is defined in Montana Code Annotated (MCA) 50-57-102 (11) (a), which states: “... *the sale or provision of food to a retail food establishment or other person engaged in retail sales who sells or provides the food directly to the consumer.*”

TABLE 1

Exemptions to wholesale food licensing under this law, but are likely subject to licensing by another agency:

<ul style="list-style-type: none">• Milk and milk product manufacturers• Raw and unprocessed fruits and vegetables• Meat packing plants• Meat slaughterhouses	<ul style="list-style-type: none">• Most foods with at least 2 percent or greater <u>cooked</u> meat, poultry by total product weight• Most foods with at least 3 percent or greater <u>raw</u> meat, poultry by total product weight
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For answers to specific licensing questions, please contact your local sanitarian or the State of Montana Department of Public Health and Human Services (DPHHS) Food and Consumer Safety Section (FCSS) at telephone number: 406-444-2837.

Question: If I only sell or distribute food directly to consumers, do I need a wholesale food license?

Answer: No, but you will likely need a retail food license, which may be obtained through a local sanitarian.

Question: If I sell or distribute food to grocery stores or other businesses, do I need a wholesale food license?

Answer: Yes, but there are exceptions, as indicated in Table 1.

Question: If I sell or distribute food to grocery stores AND consumers, do I need a wholesale food license?

Answer: Yes, but again, there are exceptions.

If selling or distributing food directly to consumers, you may also need a retail food license, depending on the type of food sold or served and where the activity takes place.

Question: If the food contains at least the percentage of meat or poultry stated in Table 1, do I need a wholesale food license?

Answer: Probably not, depending on the type of food being processed or stored, but you will likely need a different license from a state or federal agency (see Department of Livestock contact below).

NOTE: All **closed-face sandwiches** (two or more bread pieces) are DPHHS-FCSS/FDA regulated products, regardless of meat or poultry content percentage.

In most cases, if the food being processed or stored contains at least 2 percent cooked or at least 3 percent raw meat, poultry by total product weight, please contact:

State of Montana Department of Livestock

Meat and Poultry Inspection Division

P.O. Box 202001

Helena, Montana 59620-2001

Telephone: 406-444-5202

E-mail: livemail@mt.gov

Question: What is a processed food?

Answer: Processing involves many activities, but most are described Table 2 below:

Table 2
PROCESSING ACTIVITIES

<ul style="list-style-type: none">• Assembling• Baking• Bottling• Brewing• Canning• Coating• Cooking• Cutting• Distilling• Drying• Extracting	<ul style="list-style-type: none">• Fermentation• Freezing• Grinding• Heating or re-heating• Infusing• Mixing• Packaging or re-packaging• Pickling• Smoking• Stuffing• Other food treatment or food preservation process
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Table 3
PROCESSED FOOD EXAMPLES

<ul style="list-style-type: none">• Baked goods (e.g. breads, rolls, pies, pastries, brownies, crackers, etc.)• Cider• Coffee beans-roasted• Fruits-cut or dried• Herbs-cut or dried• Ice for human consumption	<ul style="list-style-type: none">• Salad mix• Salsa• Spices and spice rubs• Tea• Vegetables-cut or dried• Water for human consumption• Other processed food products
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2. SUBMIT FOOD FACILITY PLAN

Whenever a wholesale food establishment is constructed, remodeled or converted for use, written plans and specifications must be submitted to local sanitarian for review and approval, under ARM 37.110.302. Check with the local sanitarian to see if a plan review fee is charged for the service.

Question: A wholesale food license is needed. What now?

Answer: Submit a facility plan to the local sanitarian for their review and approval. The purpose of the facility plan is to ensure the business meets the physical requirements needed to produce safe food. A facility plan must include at least the following in the table below.

Table 4
FACILITY PLAN MINIMUMS

• Drawn to scale with an overhead configuration
• Legible labels, descriptions and wording on the plan
• Layout and arrangement of facility with at least: plumbing, ventilation, handwashing facilities, dishwashing facilities, food equipment and fixtures
• Construction material description for floors, walls and ceilings (i.e. ceramic tile, stainless steel, etc.)
• Type and model of food equipment and fixtures
• Water supply source (i.e. municipality name or Public Water Supply number from State of Montana Department of Environmental Quality)
• Wastewater/sewage system description (municipal, on-site system, holding tank or other system)

Replacement food equipment and utensils must meet standards specified by the National Sanitation Foundation (NSF) and/or applicable sections of the Federal Meat Inspection Act (FMIA), as required in ARM 37.110.348 (5). Business operators should look for NSF stamps or labels on equipment, fixtures and utensils.

Some local health departments may charge a fee for the plan review and have additional requirements.

Question: What construction materials may be used in the facility?

Answer: On the last page of this document in Table 10 is a listing of allowed materials for different functions.

3. SUBMIT FOOD PROCESSING PLAN AND LABELING EXAMPLES

To help determine what food safety steps may be needed for the proposed business, a food processing plan and food packaging labeling examples must be submitted to FCSS for review.

The plan and examples will be reviewed by FCSS for significant violations of the applicable state/federal rules. If significant violations are found during the review process, the proposed business will be afforded the opportunity to correct or sufficiently address the deviations in question. A satisfactory review report from FCSS is needed before issuance of a wholesale food license to operate.

Question: The facility plan was given to the local sanitarian. What now?

Answer: Create a food processing plan and submit food packaging labeling examples that has at least the following:

Table 5
FOOD PROCESSING PLAN MINIMUMS

• Supplier list— Write the origin of the raw materials for the processed food
• Product ingredient list—Write a list for each food product being processed. Each ingredient for a specific product must be listed by weight from greatest to least (in order of predominance).
• Processing method—Write what methods will be used to process the food (see Table 2)
• Packaging material—Write what containers will be used for the food (i.e. paper, plastic, metal, glass, etc.)
• Allergen list—nuts, wheat, eggs, milk, fish, soy, crustaceans must be disclosed on plan
• Distribution information—expected or anticipated shipment destinations, internet orders accepted, etc.
• Transportation provider—how and who will transport food (contract carrier vehicles, company vehicles, etc.)

Some foods or processing activities are considered higher risk for transmission of foodborne illness and may have to be reviewed by a process authority. The process authority will issue written findings, which may require the process be supervised by a qualified individual. Food manufacturers who plan to package certain foods in hermetically sealed containers are one example of processors who must obtain a process authority letter. The State of Montana recognizes two process authorities, but others may be used, if they possess proper credentials.

Table 6
PROCESSING REVIEW AUTHORITIES

Washington State University Extension Food Processing 106 FSHN, P. O. Box 646376 Pullman, WA 99164-6376 Telephone: 509-335-2845 Web: http://www.foodprocessing.wsu.edu/	Utah State University Cooperative Extension Food Safety Program 700 North 1200 East Logan, UT 84322 Telephone: 435-797-2139 Web: http://extension.usu.edu/foodsafety/htm/food-biz
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Question: What is a higher risk food or processing activity?

Answer: This question is best answered by consulting with the local sanitarian or state official.

However, certain foods in hermetically sealed containers, reduced oxygen packaging, low-acid foods and acidified foods are often cited as being higher risk for transmission of foodborne illness. The reason a consultation is often needed is because food under one condition may be safe, but under another may be much more risky in transmitting a foodborne illness. Higher risk foods or processing activities usually involve canning or bottling operations or foods containing animal products, but this is not always the case.

Question: The process plan is done. What next?

Answer: Create food packaging label examples.

Packaged and re-packaged food containers must be labeled. Labeling can be a complex issue. However, food labels must at least have the following four pieces of information:

Table 7
FOOD LABELING MINIMUMS

• Name of food product (known as the statement of identity)
• Name and address of product manufacturer, distributor or packer
• Ingredient list in order of quantity or predominance from greatest to least by weight
• Net weight or liquid volume of product in United States units of measure AND metric units of measure

PRODUCT LABELING

Please visit the United States Food and Drug Administration (FDA) web address for labeling information:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm>

A **FREE** on-line labeling course is also available. The course takes about one hour to complete:

<http://www.accessdata.fda.gov/ORAU/Labeling/>

NUTRITION LABELING

For products that require federal nutrition labeling, computer software is available to assist in creating compliant labels at the following webpage address: <http://extension.usu.edu/foodbiz/htm/nfp/>

In addition, nutrition labeling and other compliance assistance is also available from:

Mission Mountain Food Enterprise Center:

Webpage: http://www.lakecountycdc.org/Production_and_Processing_Assistance

Telephone: 406-676-5901

Question: Where is there more information on processing plans and labeling examples?

Answer: Call the state or visit their webpage for a processing and labeling checklist.

Telephone: 406-444-2408; Food and Consumer Safety Section (FCSS)

Web: <http://www.dphhs.mt.gov/publichealth/fcs/wholesalefood.shtml>

Question: The process plans and labeling examples are complete. To whom do I send the process plans and labeling examples?

Answer: The state (DPHHS-FCSS). FCSS will issue a review report of findings regarding the process plan and labeling examples. A satisfactory review report is needed for issuance of a license to operate.

Please submit completed "WHOLESALE FOOD REVIEW FORM" to:

DPHHS-FCSS

P.O. Box 202951

Helena, Montana 59620-2951

Telephone: 406-444-2837

E-mail: hhsfcs@mt.gov

4. LICENSING PROCEDURE

A wholesale food establishment license application is available through your local sanitarian. The state wholesale license fee is \$115. Check with your local sanitarian for any local fees that may apply.

Question: The process plan, labeling examples and review report were satisfactory and the business is ready. What next?

Answer: Contact your local sanitarian and schedule a pre-licensing inspection.

The local sanitarian must conduct a pre-licensing inspection and approve the license application before DPHHS issues a license to operate. A license to operate will not be granted if there are any rule violations written on the pre-licensing inspection report. Licenses are renewed on an annual basis near the end of the calendar year.

The pre-licensing inspection should be scheduled as closely to the date of opening as possible, but should also allow enough time for correction of deficiencies. All license applications and fees must be submitted before or during the pre-licensing inspection. Check with your local sanitarian for details on when fees should be submitted.

5. FDA REGISTRATION

Most wholesale food establishments must register with FDA, in accordance with the federal Bioterrorism Act of 2002. Wholesale establishments in which their primary function is selling food directly to consumers are exempt from registration under the federal code (21 CFR 1.226).

Registration on-line is easy, free and should take less than 30 minutes at the webpage address below:

<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm>

NOTE: There are businesses that charge money for registering establishments with FDA. However, this service is available for free at the above webpage address.

Question: Why do I have to register with the FDA?

Answer: For facilities that meet the criteria, the Bioterrorism Act of 2002 requires registration to be in compliance with federal law.

Table 8
LICENSING RESOURCES

Local Sanitarian Information	Montana Food and Consumer Safety Section
Web: http://www.dphhs.mt.gov/publichealth/phep/countytribalhealthdepts.shtml	Web: http://www.dphhs.mt.gov/publichealth/fcs/wholesalefood.shtml
Telephone: 406-444-2837	Telephone: 406-444-2837

Table 9
WHOLESALE FOOD LICENSE CHECKLIST

Step 1. DETERMINE WHETHER A LICENSE IS REQUIRED
Contacted local sanitarian
Contacted state Food and Consumer Safety Section (FCSS)
Step 2. SUBMIT FOOD FACILITY PLAN
Completed Food Facility Plan
Submitted Food Facility Plan to local sanitarian
Step 3. SUBMIT FOOD PROCESSING PLAN AND LABELING EXAMPLES
Completed “WHOLESALE FOOD REVIEW FORM” from FCSS, including:
List of food suppliers
Written description of how the food is delivered to the facility
Written description of how the food is stored until it is processed
List of ingredients for foods being processed
Written description of how foods will be processed and with what equipment
Written description of how the food will be packaged
List of allergens in the facility and what equipment is used to process allergens
Written description of how food will be stored until being shipped
Written description of how and when equipment is cleaned and sanitized
Written description of how and when facility is cleaned (floor, walls, ceiling, etc.)
Distribution information about food (where will the food be shipped)
Transportation provider for food (contract carrier, fleet vehicle, etc.)
Written description of water source
Completed food labeling examples
Submitted food labeling examples to FCSS
Submitted “WHOLESALE FOOD REVIEW FORM” to FCSS
Obtained satisfactory review report from FCSS for food processing plan and labeling examples
Step 4. LICENSING PROCEDURE
Completed wholesale food business application
Contacted local sanitarian for pre-licensing inspection
Paid applicable fees
Step 5. FDA REGISTRATION
Registered business with FDA (if not specifically exempted from registering in 21 CFR 1.226)

Legal references: 50-57-102 (11)(a), MCA; 50-57-201, MCA; 37.110.101, ARM; 37.110.301 et seq., ARM

Table 10
ALLOWED AND UNALLOWED BUILDING MATERIALS

Establishment Area	Floor			Basecove			Wall					Ceiling				
	Rubber	Ceramic Tile/Quarry Tile	Epoxy Resin	Coved Ceramic/Quarry Tile	Vinyl Screed	Stainless Steel	Commercial Rubber Base Cove for rubber flooring	Stainless Steel	Ceramic Tile	Fiberglass Reinforced Panel	Epoxy-painted Concrete Block	Painted Drywall	Metal—Non-galvanized	Painted Drywall	Vinyl-coated Acoustic Tile	Open joists and rafters
Food process/prep	●	A	●	A	—	A	●	A	A	A	A	U	●	A	A	U
Cooking/Baking	●	A	●	A	—	A	●	A	A	U	●	U	●	A	A	U
Dishwashing	●	A	●	A	—	A	●	A	A	A	A	U	●	A	A	U
Handwashing station	●	A	●	A	—	A	●	A	A	A	A	U	●	A	A	U
Walk-in cooler/freezer	U	A	●	A	A	A	U	—	—	—	—	—	—	—	—	—
Buffet	●	A	●	A	—	A	●	A	A	A	A	U	●	A	A	U
Server station for food	●	A	●	A	—	A	●	A	A	A	A	U	●	A	A	U
Bar service	●	A	●	A	—	A	●	A	A	A	A	●	●	A	A	*
Dry food storage	●	A	●	A	—	A	●	A	A	A	A	A	●	A	A	▼
Janitorial station	●	A	●	A	—	A	●	A	A	A	A	U	●	A	A	●
Worker toilet room	●	A	●	A	—	A	●	A	A	A	A	A	A	A	A	U

A	=	Allowed
U	=	Unallowed
●	=	Seek approval from regulatory authority prior to installation
—	=	Not applicable, must meet National Sanitation Foundation and/or Federal Meat Inspection Act standards
*	=	Sealed joists, rafters and beams may be approved to accommodate for aesthetics
▼	=	Allowed for unopened containers of food, beverages and single-service food items